

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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SECURITIES AND EXCHANGE :
COMMISSION, :
 :
Plaintiff, : Civil Action
 : No. 05-11805-NMG
v. :
 :
RICHARD F. SELDEN, :
 :
Defendant. :
----- X

U.S. DISTRICT COURT
DISTRICT OF MASS.

**RICHARD F. SELDEN'S
UNOPPOSED MOTION TO IMPOUND**

Richard F. Selden ("Dr. Selden") hereby moves, unopposed, pursuant to Local Rule 7.2 of this Court, for an Order permitting (i) Richard F. Selden's Motion For Summary Judgment On All Counts And An Award Of Attorneys' Fees Against The Securities And Exchange Commission; (ii) Richard F. Selden's Memorandum Of Law In Support Of His Motion For Summary Judgment On All Counts And An Award Of Attorneys' Fees Against The Securities And Exchange Commission; (iii) Richard F. Selden's Local Rule 56.1 Statement Of Material Facts As To Which There Is No Genuine Issue To Be Tried; and (iv) the Transmittal Affidavit Of Justin J. Daniels In Support Of Richard F. Selden's Motion For Summary Judgment On All Counts And An Award Of Attorneys' Fees Against The Securities And Exchange Commission (the "Confidential Documents") to be filed under seal and impounded until further order of the Court:

As grounds for this unopposed motion, Dr. Selden states as follows:

1. A related proceeding captioned In re Subpoenas In S.E.C. v. Richard F. Selden, Misc. Case No. 1:05-mc-00476-RMU (D.D.C.) is pending in the U.S. District Court for the District of Columbia.

2. In that proceeding, on November 21, 2006, the court entered a protective order stating that “Any submissions to this Court or to the Court in [this action] that refer to or describe [confidential FDA] material . . . are to be marked ‘Confidential FDA Material’ and are not to be placed in the public file or on public record without the prior written consent of the FDA.” Protective Order Governing The Production Of FDA Documents, at 6 (S.E.C. v. Selden, Misc. Case No. 1:05-mc-00476-RMU) (D.D.C. Nov. 21, 2006) (attached hereto as Exhibit A). On July 16, 2007, the court entered a supplemental protective order stating that “Any submissions to the Courts in [the D.D.C. action or this action] that refer to or describe [confidential FDA testimony] are to be marked ‘Confidential FDA Material’ and are not to be placed in the public file or on public record without the prior written consent of the FDA.” Supplemental Protective Order, at 4 (S.E.C. v. Selden, Misc. Case No. 1:05-mc-00476-RMU) (D.D.C. July 16, 2007) (attached hereto as Exhibit B).

3. The Confidential Documents refer to certain confidential and non-public FDA materials and testimony.

4. FDA has not provided written consent to place the Confidential Documents in the public file or on the public record.

5. By this motion, Dr. Selden respectfully requests leave to file the Confidential Documents under seal, such that the Court has the benefit of the information and materials contained therein.

6. Dr. Selden has served upon opposing counsel a copy of the Confidential Documents, so that the SEC will not be prejudiced by the time that elapses between the filing of this motion and the ruling of the Court on this motion.

7. In accordance with Local Rule 7.2(a), which requires that a motion to impound "contain a statement of the earliest date on which the impounding order may be lifted," Dr. Selden suggests that at the conclusion of the litigation, after any appeals have been exhausted, the impounded Confidential Documents be returned to Dr. Selden's undersigned counsel.

WHEREFORE, Dr. Selden respectfully requests that the Court allow his Motion to Impound.

LOCAL RULE 7.1(A)(2) CERTIFICATION

The undersigned counsel hereby certifies that counsel for Dr. Selden has conferred with opposing counsel and that they do not oppose the relief sought by this motion.

Dated: January 2, 2008
Boston, Massachusetts

Respectfully submitted,



Thomas J. Dougherty (BBO #132300)
Justin J. Daniels (BBO #656118)
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Counsel for Richard F. Selden

CERTIFICATE OF SERVICE

I, Justin J. Daniels, hereby certify that on January 2, 2008, I caused a true copy of the foregoing to be served by hand delivery upon Frank C. Huntington, counsel for the plaintiff Securities and Exchange Commission, Boston District Office, 33 Arch Street, 23rd Floor, Boston, Massachusetts 02110.

Dated: January 2, 2008



Justin J. Daniels

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

IN RE SUBPOENAS IN:

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SECURITIES AND EXCHANGE	:
COMMISSION,	:
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Piaintiff,	:
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	:
v.	:
	:
RICHARD F. SELDEN,	:
	:
Defendant,	:
	:
and,	:
	:
FOOD AND DRUG ADMINISTRATION,	:
	:
Interested Party.	:
-----X	

Miscellaneous Case No. 05-00476-RMU

(Related Cases:
Civ. No. 05-11805-NMG
Civ. No. 06-11807-NMG
Pending in the United States District
Court for the District of Massachusetts)

PROTECTIVE ORDER
GOVERNING THE PRODUCTION OF FDA DOCUMENTS

Upon consideration of the Joint Motion For Protective Order Governing The Production Of FDA Documents, filed by Richard F. Selden ("Dr. Selden") and the United States Food and Drug Administration ("FDA") (collectively, the "Parties"), and upon consideration of all papers and proceedings herein, it is this 21st day of November, 2006,

ORDERED that the Joint Motion is **GRANTED**, and it is

FURTHER ORDERED that:

As negotiated by the Parties, FDA shall produce to Dr. Selden all documents within the FDA's possession, custody, or control on the terms and under the deadlines provided below, with such documents to be produced in reasonable increments on a rolling basis as they become available for production:

Subject	Negotiated FDA Production	Deadline
A. Replagal, Transkaryotic Therapies, Inc. ("TKT") and Dr. Selden.	<ul style="list-style-type: none"> - All documents (e.g., internal records, correspondence, e-mail and computer files) relating to Replagal (including both the BLA and all INDs), TKT or Dr. Selden, <u>excluding</u>: (i) documents submitted by TKT and (ii) TKT documents relating to a product other than Replagal. - All Jan. 2003 FDA Advisory Committee documents relating to Replagal, <u>excluding</u>: (i) documents submitted by TKT and (ii) documents publicly available at http://www.fda.gov/ohrms/dockets/ac/cder03.html#EndocrinologicMetabolicDrugs. - All FDA documents relating to the SEC Action or any other lawsuit involving Replagal, TKT or Dr. Selden, <u>excluding</u> documents submitted by Dr. Selden. 	Dec. 31, 2006
B. Complete Response Letters ("CRLs").	<ul style="list-style-type: none"> - All CRLs (for both approved and unapproved products) issued by CBER between Jan. 1, 1998 and Dec. 31, 2002, inclusive, <u>excluding</u> CRLs for BLA "supplements" and BLA "non-user fee" products (see 21 U.S.C. § 379g(1)). 	May 15, 2007
C. Fabrazyme.	<ul style="list-style-type: none"> - All documents (e.g., internal records, correspondence, e-mail and computer files) relating to Fabrazyme (including both the BLA and all INDs), <u>excluding</u>: (i) documents relating exclusively to CMC; (ii) documents publicly available at http://www.fda.gov/cder/biologics/products/agalgen042403.htm; (iii) documents generated after Apr. 23, 2003; and (iv) documents receiving special treatment (see below). - All Jan. 2003 FDA Advisory Committee documents relating to Fabrazyme, <u>excluding</u> documents publicly available at http://www.fda.gov/ohrms/dockets/ac/cder03.html#EndocrinologicMetabolicDrugs. - Fabrazyme documents receiving special treatment: <ol style="list-style-type: none"> (1) For Genzyme's June 2000 BLA for Fabrazyme, FDA will produce only the main reports from the sections previously indicated by Dr. Selden, and also agrees to produce on an expedited basis any additional exhibits or attachments based on any reasonable request by Dr. Selden. (2) For Genzyme's written responses to FDA's CRLs for Fabrazyme, FDA will produce only Genzyme's substantive responses to each of the questions/items in the CRL, and also 	May 15, 2007

Subject	Negotiated FDA Production	Deadline
D. Internal review guidelines.	<p data-bbox="512 388 1181 483">agrees to produce on an expedited basis any additional exhibits or attachments based on any reasonable request by Dr. Selden.</p> <ul data-bbox="512 483 1181 997" style="list-style-type: none"> - CBER's New Reviewer training materials available for reference or use during the period June 1, 2000 through May 31, 2001. In addition, FDA also agrees to produce on an expedited basis any additional sections of the New Reviewer materials for the periods Jan. 1, 1998 through May 31, 2000 and June 1, 2001 through Apr. 23, 2003, based on any reasonable request by Dr. Selden. - CBER's internal review manuals available for reference or use during the period June 1, 1998 through Apr. 23, 2003. - All other guidelines, manuals, templates, and training materials for CBER review of BLAs, INDs, trials, protocols, etc. that were available for reference or use during the period June 1, 2000 through Dec. 31, 2002. 	May 15, 2007
E. Record retention schedules.	<ul data-bbox="512 1008 1181 1113" style="list-style-type: none"> - FDA's Headquarters Record Control Schedule, last updated on Dec. 31, 1989, which FDA represents was and is the applicable record retention schedule for 1990 to present. 	Production Complete
F. FDA guidance on public disclosure of status.	<ul data-bbox="512 1123 1181 1155" style="list-style-type: none"> - The FDA states that it has no responsive documents. 	N/A
G. FDA/SEC coordination.	<ul data-bbox="512 1270 1181 1302" style="list-style-type: none"> - All responsive documents. 	Dec. 31, 2006
H. Remaining Requests.	<ul data-bbox="512 1344 1181 1375" style="list-style-type: none"> - No production necessary. 	N/A

¹²³⁴⁵⁶⁷⁸tion, the productions referenced above shall be governed by the following

terms and conditions:

1. All documents produced pursuant to this Order may be used only in connection with S.E.C. v. Richard F. Selden, Civ. No. 05-11805-NMG (D. Mass.) ("SEC Action") and S.E.C. v. Richard F. Selden, Misc. Case No. 05-00476-RMU (D.D.C.). Documents produced pursuant to this Order shall not be disclosed or revealed in any way outside of those actions.

2. Some categories of documents to be produced pursuant to this Order contain non-public information, including confidential commercial or financial information, submitted to FDA by third parties. FDA will produce such documents pursuant to the terms of this Order and in accordance with applicable law (see, e.g., 21 U.S.C. § 331(j); 18 U.S.C. § 1905; 21 C.F.R. § 20.61) and FDA procedures.

3. In addition to the restrictions set forth in paragraph 1, above, if the FDA produces documents containing unredacted privileged or confidential third-party commercial or financial information (as those terms are defined in 21 C.F.R. § 20.61), such documents shall be governed by the following additional terms:

a. Upon production of such documents, the FDA shall notify Dr. Selden in writing which documents are subject to this paragraph 3.

b. The right of access to documents subject to this paragraph 3 is limited to the following persons: (a) attorneys and parties in the SEC Action; (b) medical and analytical experts, not employed by any drug manufacturer, whose review of the material is deemed essential to the preparation or presentation of the defense in the SEC Action; and (c) such law

¹ See 10/28/05 Subpoenas, Sch. A, Request Nos. 1, 2, 4, 6 & 8.

² See id. No. 3.

³ See id. Nos. 1, 2 & 7.

⁴ See id. No. 9.

⁵ See id. No. 10.

⁶ See id. No. 12.

⁷ See id. No. 13.

⁸ See id. Nos. 5 & 11.

clerks, paralegals, secretaries, and consultants whose review of this material is deemed essential to the preparation or presentation of the defense in the SEC Action.

c. Prior to review of the material described in this paragraph 3, each person who is not a government employee or attorney in the SEC Action shall sign and date a copy of the following statement:

I acknowledge access to confidential material ("protected material") received pursuant to a Protective Order issued in the miscellaneous civil action entitled S.E.C. v. Richard F. Selden, Misc. Case No. 05-00476-RMU (D.D.C.), for purposes of production in the related action entitled S.E.C. v. Richard F. Selden, Civ. No. 05-11805-NMG (D. Mass.) ("SEC Action"). I certify my understanding that I will be in violation of that Protective Order and will be subject to contempt of court proceedings if I do not abide by the following requirements:

All notes pertinent to the protected material must, when not in my personal custody, either be returned to another person authorized under the Protective Order to review the protected material, or must be stored in a locked repository (such as a locked desk drawer or locked file) for which I must maintain personal custody of keys or combinations thereto.

I may grant access to my notes only to those individuals who are authorized under the Protective Order to review the protected material.

I must return all notes pertinent to the protected material to the attorneys who provided access to the material upon termination of this case, when my need for the information with respect to this case no longer exists, or upon order of the Court, whichever occurs first.

I must report in writing to the Court in the SEC Action all incidents in which unauthorized persons might have gained access to my notes about the protected material.

I must not release, publish, disclose or use for any purpose (other than for the preparation or testimony in any hearing or trial in the SEC Action) this protected material, and specifically any of the facts contained therein or any information derived therefrom.

One copy of each such statement shall be provided to counsel for the FDA within 30 days after the conclusion of the SEC Action.

d. Any submissions to this Court or to the Court in the SEC Action that refer to or describe material subject to this paragraph 3 are to be marked "Confidential FDA Material" and are not to be placed in the public file or on public record without the prior written consent of the FDA.

e. All material subject to this paragraph 3 must either be returned to counsel for the FDA or destroyed at such time as it is not further needed in the SEC Action, at the conclusion of the SEC Action, or upon order of the court, whichever occurs first. If the persons in possession of such material opt to destroy it, they shall certify in writing to FDA, within five (5) days of destruction, that all such material has been destroyed.

6. If a document is redacted or withheld from production on the basis of the deliberative process privilege,⁹ the FDA shall, within 30 days of production (in the case of redaction) or decision to withhold (in the case of withholding) provide Dr. Selden with a "Vaughn index"¹⁰ covering such documents. With respect to documents redacted or withheld on bases other than the deliberative process privilege, the FDA shall provide its Vaughn index within 90 days.

SO ORDERED.

RICARDO M. URBINA
United States District Judge

⁹ See Judicial Watch, Inc. v. FDA, 449 F.3d 141, 150-52 (D.C. Cir. 2006).

¹⁰ See Vaughn v. Rosen, 484 F.2d 820 (D.C. Cir. 1973).

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE SUBPOENAS IN:

ECF

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SECURITIES AND EXCHANGE	:	
COMMISSION,	:	
	:	
Plaintiff,	:	Miscellaneous Case No. 05-00476-RMU
	:	
v.	:	(Related Cases:
	:	Civ. No. 05-11805-NMG
RICHARD F. SELDEN,	:	Civ. No. 06-11807-NMG
	:	Pending in the United States District
Defendant,	:	Court for the District of Massachusetts)
	:	
and,	:	
	:	
FOOD AND DRUG ADMINISTRATION,	:	
	:	
Interested Party.	:	
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SUPPLEMENTAL PROTECTIVE ORDER

Upon consideration of the Joint Motion For Supplemental Protective Order, filed by Richard F. Selden ("Dr. Selden") and the United States Food and Drug Administration ("FDA") (collectively, the "Parties"), and upon consideration of all papers and proceedings herein, it is this 16th day of July, 2007,

ORDERED that the Joint Motion is GRANTED, and it is

FURTHER ORDERED that:

1. All testimony provided pursuant to this Supplemental Protective Order may be used only in connection with S.E.C. v. Richard F. Selden, Civ. No. 05-11805-NMG (D. Mass.), and S.E.C. v. Richard F. Selden, Misc. Case No. 05-00476-RMU (D.D.C.)

(the "SEC actions") and may not be disclosed or revealed in any way outside of those actions.

2. Some testimony provided pursuant to this Supplemental Protective Order may contain non-public information, including confidential commercial or financial information, submitted to FDA by third parties. FDA will provide such testimony pursuant to the terms of this Supplemental Protective Order and in accordance with applicable law (see, e.g., 21 U.S.C. § 331(j); 18 U.S.C. § 1905; 21 C.F.R. § 20.61) and FDA procedures.

3. In addition to the restrictions set forth in paragraph 2, above, if the FDA witnesses provide testimony revealing privileged or confidential third-party commercial or financial information (as those terms are defined in 21 C.F.R. § 20.61), or information subject to FDA's deliberative process privilege, such information shall be governed by the following additional terms:

a. Transcripts, video and audio recordings, and any other records containing information obtained from the testimony of the FDA witnesses are subject to this paragraph 3.

b. The right of access to records subject to this paragraph 3 is limited to the following persons: (a) attorneys and parties in the SEC Actions; (b) medical and analytical experts, not employed by any drug manufacturer, whose review of the records is deemed essential to the preparation or presentation of the defense in the SEC Actions; and (c) such law clerks, paralegals, secretaries, and consultants whose review of the records is deemed essential to the preparation or presentation of the defense in the SEC Actions.

c. Prior to review of the records described in this paragraph 3, each person who is not a government employee or attorney in the SEC Actions shall sign and date a copy of the following statement:

I acknowledge access to confidential material ("protected material") received pursuant to a Protective Order issued in the miscellaneous civil action entitled S.E.C. v. Richard F. Selden, Misc. Case No. 05-00476-RMU (D.D.C.), for purposes of production in the related action entitled S.E.C. v. Richard F. Selden, Civ. No. 05-11805-NMG (D. Mass.) ("SEC Actions"). I certify my understanding that I will be in violation of that Protective Order and will be subject to contempt of court proceedings if I do not abide by the following requirements:

All notes pertinent to the protected material must, when not in my custody, either be returned to another person authorized under the Protective Order to review the protected material, or must be stored in a locked repository (such as a locked desk drawer or locked file) for which I must maintain custody of keys or combinations thereto.

I may grant access to my notes only to those individuals who are authorized under the Protective Order to review the protected material.

I must return all notes pertinent to the protected material to the attorneys who provided access to the material upon termination of this case, when my need for the information with respect to this case no longer exists, or upon order of the Court, whichever occurs first.

I must report in writing to the Court in the SEC Actions all incidents in which unauthorized persons might have gained access to my notes about the protected material.

I must not release, publish, disclose or use for any purpose (other than for the preparation or testimony in any hearing or trial in the SEC Actions) this protected material, and specifically any of the facts contained therein or any information derived therefrom.

One copy of each such statement shall be provided to counsel for the FDA within 30 days after the conclusion of the SEC Action.

d. Any submissions to the Courts in the SEC Actions that refer to or describe the records subject to this paragraph 3 are to be marked "Confidential FDA Material" and are not to be placed in the public file or on public record without the prior written consent of the FDA.

e. All records subject to this paragraph 3 must either be returned to counsel for the FDA or destroyed at such time as they are not further needed in the SEC Actions, at the conclusion of the SEC Actions, or upon order of the court, whichever occurs first. If the persons in possession of such records opt to destroy the records, they shall certify in writing to FDA, within five (5) days of destruction, that all such records have been destroyed.

4. FDA shall permit Dr. Selden to depose FDA employees Drs. James Kaiser, Rafel Rieves, Marc Walton, and Karen Weiss for use in the SEC Action. These four employees will testify regarding only:

- a. FDA's review of TKT's INDs and/or BLA for Replagal;
- b. FDA's review of Genzyme's INDs and/or BLA for Fabrazyme;
- c. FDA's drug/biologics approval process in general; and
- d. Communications and/or coordination with the SEC relating to TKT, Replagal, and/or Dr. Selden.

5. FDA shall permit Dr. Selden to depose FDA employees Dr. Marc Walton and Mr. David Krawetz, pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, for use in the SEC Actions.

a. Dr. Walton will testify regarding only FDA's communication, consultation, and/or coordination with other governmental agencies, including but not limited to the SEC, related to TKT, Dr. Selden and/or the SEC Actions, which occurred prior to October 28, 2005.

b. Mr. Krawetz will testify regarding only FDA's responses to subpoenas for documents issued by Dr. Selden to FDA on or about October 28, 2005, and/or any court orders relating thereto, including but not limited to: (i) the responses of the Office of Chief Counsel; (ii) the responses of the Office of Enforcement; (iii) a general description of FDA's search for documents; (iv) a general description of FDA's collection and review of documents; (v) any communication, consultation, and/or coordination with anyone at SEC or any other governmental agencies with respect to TKT, Dr. Selden, and/or any of the above, which occurred on October 28, 2005 or later.

6. The FDA employees will not answer questions beyond the scope of the testimony authorized above and are explicitly prohibited from testifying with respect to:

a. Trade secrets or confidential commercial or financial information held by third-party companies, individuals, or entities, unless the disclosure of such information (i) has been authorized by the third-party, (ii) is provided for by applicable regulations, or (iii) has been provided for pursuant to this Supplemental Protective Order;

b. Attorney-client communications;

c. Information subject to FDA's deliberative process privilege, unless it relates to any of the specific topics above, upon which such witness's testimony has been authorized;

d. Any other non-public information the release of which is not provided for pursuant to this Supplemental Protective Order or is provided for by applicable regulations; and

e. Expert opinions on any matter.

7. The depositions of the FDA employees shall take place at locations and at times mutually agreeable to the Parties, except that in no event shall a deposition be scheduled to take place after the fact discovery cut-off date in the SEC Action in the District of Massachusetts presently set for September 13, 2007. Each of the five depositions identified in paragraphs 4 and 5 above (Kaiser, Rieves, Walton, Weiss and 30(b)(6)) shall take place once, shall not exceed seven (7) total hours per deposition, and may be videotaped for use at trial in lieu of the witness's appearance.

8. FDA shall waive its deliberative process privilege for information contained in testimony that is subject to production under this Supplemental Protective Order and for documents subject to production under the Protective Order Governing The Production Of FDA Documents entered by the Court in this matter on November 21, 2006, except that FDA shall be entitled to assert its deliberative process privilege with respect to information concerning: (1) exclusively "CMC"; (2) FDA inspections of third-party manufacturing facilities, but not including facilities operated or maintained by Quintiles, Inc.; and (3) FDA's review of products other than Replagal and Fabrazyme. Documents or information previously withheld or redacted from production by FDA on the basis of the deliberative process privilege are now subject to immediate production to Dr. Selden.

SO ORDERED.



UNITED STATES DISTRICT JUDGE

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